

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Electromedicarin, S.A.

2-Address: Poligono Industrial "Can Volart"
C/Torre de Cellers, 6 – 08150 Partes del Vallés
Barcelona / Spain

3-Phone: +34 / 93 573 07 24 / 86 / 91

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5-Contact Person: Mr Rafael Barba Trujillo (General Manager)

6-Date summary prepared: February 10th, 2003

7- Official Correspondent: Mansour Consulting

8- Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA

9- Phone: (678) 908-8180

10- Fax: (425) 795-9341

11- Contact person: Jay Mansour, president

12-Device Trade or Proprietary Name: ELECTROMEDICARIN 900

13-Device Common or usual name: Electrostimulator

14-Device Classification Name: Stimulator, Muscle, Powered

15-Substantial Equivalency is claimed against the following device:

*Rich-Mar Corporation's Winner ST4 Stimulator, 510k #k000808
(refer to Appendix 2 for FDA website printout)*

***This notification for ELECTROMEDICARIN 900 is of the
ABBREVIATED type as per the declaration of conformity included
in this summary***

16-Description of the Device:

The Unit **ELECTROMEDICARIN 900** is a 3-channel electrostimulator of low and medium frequency currents.

The 3 output channels makes possible to treat 3 patients at the same time or synchronize several muscle groups. The unit is controlled by a microprocessor which allows a wide variation of parameters in order to work with the optimal currents all the time and for each patient: pulse width, bursts, relaxation time, time of increasing and decreasing ramps, modulation frequency, vector type,... See all types of waveforms in "Technical Characteristics".

Also, the user can save his/her own parameters in non-volatile memory.

The unit has a 320x240 pixels monochrome (white and blue) LCD of 9" and the Menu options and intensity are selected by means of endless encoders. The end of the treatment is notified with a melody or a sequence of beeps.

17-Intended use of the device: *(Indications for use typed on a separate FDA form)*

This device is an electrically powered device intended for medical purposes to repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected area (21 CFR 890.5850) for the following indications for use: relaxation of muscle spasms; prevention or retardation of disuse atrophy; increasing local blood circulation; muscle re-education; immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and maintaining or increasing range of motion

18-Safety and effectiveness of the device:

This device is safe and effective as the predicate device **Winner ST4 Stimulator**.

This is better expressed in the tabulated comparison (Paragraph 19 below)

19-Summary comparing technological characteristics with other predicate device:

PREDICATE DEVICE : WINNER ST4 STIMULATOR

Manufacturer: Rich-Mar Corporation

510(k) Number: K000808

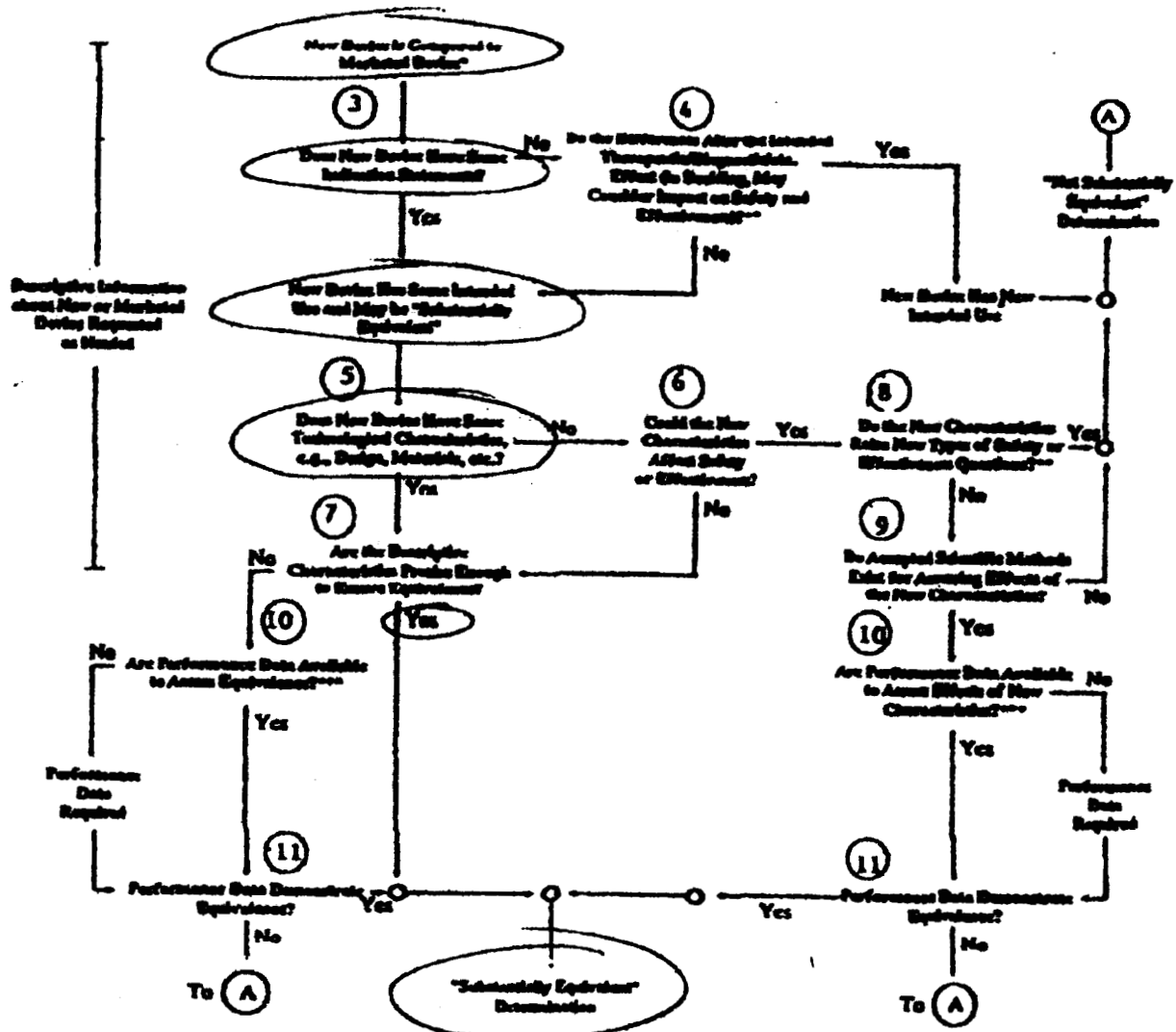
Please find below a tabulated comparison supporting that **ELECTROMEDICARIN 900** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency detailed chart path is attached.

FDA file reference number	510k 000808
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	Comparison result
Indications for use	Identical
Target population	Identical
Materials	Similar
	PREDICATE DEVICE
	metal cabinet with plastic panel
	ELECTROMEDICARIN 900
	lower metallic chassis with plastic front cover
Performance	Similar
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Number of channels	Similar
	PREDICATE DEVICE
	4
	ELECTROMEDICARIN 900
	3
Output Waveforms	Similar
	PREDICATE DEVICE
	Quadpolar IFC
	ELECTROMEDICARIN 900
	Quadpolar IFC (called <i>Tetrapolar Interferentials</i>)

	Pre-Mod IFC	Pre-Mod IFC (called <i>Bipolar Interferentials</i>)
	Hi-Volt	Hi-Volt (called <i>Rectangular Pulses</i>)
	Russian	Russian (called <i>MEGAA current</i>)
	Microcurrent (0.3Hz to 1000Hz)	Microcurrent (1Hz to 200Hz)
	Similar	
Basic Unit Characteristics	Similar	
	Characteristic	PREDICATE DEVICE
	Power Source	120VAC / 60Hz
	Method of Line Current Isolation	-unknown-
	Patient Leakage Current	
	- normal condition	< 100 μ A
	- single fault condition	< 500 μ A
	Number of Output Modes	1 (Regulated Current Mode)
	Number of Output Channels	4
	- synchronous or alternating	synchronous
	- method of channel isolation	-unknown-
	Software/Microprocessor control	Yes
	Automatic Overload Trip	Yes
	Automatic No-Load Trip	Yes
	Automatic Shut Off	No
	Patient Override Control	No
	Indicator Display	
	- On/Off Status	Yes
	- Voltage/Current level	Yes
	Timer Range	30
	Compliance with Voluntary Standards?	-
	Compliance with 21CFR 898?	Yes
	Weight	9 lbs
	Dimensions (inches) [W x H x D]	15" x 5.5" x 9"
	Housing Materials and Construction	metal cabinet with plastic panel
		lower metallic chassis with plastic front cover
Output Specifications	Similar	
	Characteristic	PREDICATE DEVICE
	Maximum Output Voltage (\pm 5%) (for all waveforms)	\pm 150V @ 500 Ω \pm 150V @ 1000 Ω
		ELECTROMEDICARIN 900 \pm 150V @ 500 Ω \pm 150V @ 1000 Ω

	Maximum Output Current ($\pm 5\%$) - pulsed monophasic, biphasic and sinusoidal - exponentials and galvanic	$\pm 90 \text{ mA @ } 500\Omega$ $\pm 90 \text{ mA @ } 1000\Omega$ -	$\pm 90 \text{ mA @ } 500\Omega$ $\pm 90 \text{ mA @ } 1000\Omega$ $\pm 70 \text{ mA @ } 500\Omega$ $\pm 70 \text{ mA @ } 1000\Omega$
	Pulse Width (μs)	10 to 500	20 to 500
	Frequency (Hz)	0.3 to 1000	1 to 200
	Interferential Beat Frequency (Hz)	unknown	1 to 250
	Multiphasic Waveforms - symmetrical phases - phase duration (ms) - net charge (μC per pulse) - maximum phase charge (μC)	Yes 1 to 3300 0 (compensated pulse) 45	Yes 5 to 1000 0 (compensated pulse) 45
	Maximum current density (mA/cm^2)	2	2
	Burst Mode - ON Time (seconds) - OFF Time (seconds)	5 - 10 5 - 10 - 20 - 30 - 50	1 to 25 1 to 25
	Energy used and/or delivered	Similar (see Output Specifications)	
	Compatibility with environment and other devices	Identical	
	Where used	Identical	
Standards met		Identical (IEC 60601-1: Safety of Medical Electrical Equipment)	
Electrical safety		Identical (Class I, Type BF units)	
Thermal safety		Identical	

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 17 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jay Mansour
Mansour Consulting, LLC
Representing Electromedicarin, S.A.
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K020478
Trade/Device Name: Electromedicarin 900
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Codes: IPF
Dated: May 28, 2003
Received: June 2, 2003

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

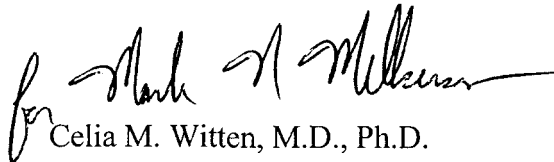
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark A. Witten".

Celia M. Witten, M.D., Ph.D.

Director

Division of General, Restorative, and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K020478

Device Name: ELECTROMEDICARIN 900

Indications for Use:

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for Mark N. Miller

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020478

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)